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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,176	09/23/2003	Kari Alitalo	28967/37564B	4378

4743 7590 03/27/2006

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EXAMINER

BORGEEST, CHRISTINA M

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,176

Applicant(s)

ALITALO ET AL.

Examiner

Christina Borgeest

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 (in part), 3-5, 11-14 (in part) are drawn to methods of administering a composition comprising a vascular endothelial growth factor C (VEGF-C) protein or a vascular endothelial growth factor D (VEGF-D) protein, classified in class 514, subclass 2.
- II. Claims 1-2 (in part), 6-10, 11-14 (in part) are drawn to methods of administering a VEGF-C polynucleotide or VEGF-D polynucleotide, classified in class 514, subclass 44.
- III. Claim 15 is drawn to purified and isolated neural cells, classified in class 435, subclass 325.
- IV. Claims 16-22 are drawn to methods of administering neural stem cells, classified in class 424, subclass 93.1.
- V. Claims 23-28 (in part) are drawn to methods of administering a VEGF-C or VEGF-D protein and a neural growth factor, classified in class 514, subclass 2.
- VI. Claims 23-28 (in part), drawn to methods of administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor, classified in class 514, subclass 44.

- VII. Claims 29-31 (in part) are drawn to methods of administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent, classification dependent upon recited "agent".
- VIII. Claims 29-31 (in part) are drawn to methods of administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent, classification dependent upon recited "agent".
- IX. Claims 32-34 are drawn to methods of administering of a VEGF-C inhibitor, classification dependent upon recited "inhibitor".
- X. Claim 35 (in part) is drawn to a composition comprising a VEGF-C protein and a neural growth factor, classified, for example, in class 514, subclass 44.
- XI. Claim 35 (in part) is drawn to a composition comprising a VEGF-C polynucleotide and a neural growth factor, classified, for example, in class 514, subclass 44.
- XII. Claim 36 (in part) is drawn to a composition comprising a VEGF-C protein and a neurotherapeutic agent, classification dependent upon said "agent".
- XIII. Claim 36 (in part), drawn to a composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent, classification dependent upon said "agent".

Inventions I and II, VI, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of administering compositions comprising a VEGF-C or VEGF-D protein (Group I) is distinct from methods of administering a VEGF-C polynucleotide (Group II), administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor (Group VI) or administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent (Group VIII). The methods of Group I encompass protein therapy, whereas the scope of Groups II, VI and VIII is limited to administration of polynucleotides. The methods are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The method of administration of a polynucleotide comprise distinct steps and utilize different products than a method that comprises administration of a polypeptide. Each invention performs this function using a structurally and functionally divergent material, therefore, each method is divergent in materials and steps. For these reasons the Inventions I and II, VI, VIII are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and III are unrelated. The product of Group III (purified and isolated neural cells) would not be used in the method of Group I, which is drawn to the

administration of proteins. Likewise, Inventions I and IV are unrelated. The method of administering compositions comprising a VEGF-C or VEGF-D protein (Group I) is distinct from a method of administering neural stem cells (Group IV). The method of administration of neural stem cells comprise distinct steps and utilize different products than a method that comprises administration of a polypeptide or a polynucleotide. The methods of inventions I and III and I and IV are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I and IV are patentably distinct. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and V, VII are directed to related but distinct methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have materially different design, mode of operation, function, or effect. See MPEP § 806.05 (j). In the instant case, Groups V (administering a VEGF-C or VEGF-D protein and a neural growth factor) and VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent) each are drawn to the administration of a VEGF-C or VEGF-D protein **and an additional agent**. Restriction is deemed to be proper because the

method steps in Groups I and V, VII are not co-extensive, in other words there is an extension of search for each of the three methods, thus a search and examination of all three methods in one patent application would result in an undue burden. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and VI, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group VI is drawn to methods of administration of a VEGF-C or VEGF-D polynucleotide and a neural growth factor, Group VIII is drawn to methods of administration of a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent and Group IX is drawn to methods of administration of a VEGF-C inhibitor, whereas Group I is drawn to administration of a VEGF-C OR VEGF-D protein. Group I encompasses protein therapy, whereas Groups VI and VIII encompass gene therapy and Group IX encompasses administration of a VEGF-C inhibitor. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and X-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups X (composition comprising a VEGF-C protein and a neural growth factor), XI (composition comprising a VEGF-C polynucleotide and a neural growth

factor), XII (composition comprising VEGF-C protein and a neurotherapeutic agent) and XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are not disclosed as being used for the method of Group I (administering a composition comprising a vascular endothelial growth factor C (VEGF-C) protein or a vascular endothelial growth factor D (VEGF-D) protein), thus the searches would not be co-extensive. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the product of Group III (purified and isolated neural cells) is not necessary to carry out the methods of Group II (administering a VEGF-C or VEGF-D polynucleotide), thus the inventions are distinct. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and IV, V, VII, IX are all unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of administering a VEGF-C or VEGF-D polynucleotide (Group II) is distinct from methods of administering neural stem cells (Group IV), a VEGF-C or VEGF-D protein and a neural growth factor (Group V) a VEGF-C or VEGF-D protein and a neurotherapeutic agent (Group VII) and a VEGF-C inhibitor (Group IX). The methods are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group II, which encompasses gene therapy, comprises distinct steps and utilize different products than methods comprising cell (Group IV) protein (Groups V, VII) or antagonist (IX) therapies, for example. Each invention performs this function using a structurally and functionally divergent material, and each method is divergent in materials and steps. For these reasons the Inventions II and IV, V, VII, IX are patentably distinct. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and VI, VIII, XI and XIII are directed to related but distinct inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group II is drawn to methods of administering a VEGF-C polynucleotide or VEGF-D polynucleotide, which is distinct from Groups VI (administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor) and VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent). The methods are drawn to methods of administering a VEGF-C or VEGF-D polynucleotide **and an additional product**, thus there is an extension of search for each of the methods. Similarly, the products of Groups XI (composition comprising a VEGF-C polynucleotide and a neural growth factor) and XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are not those recited in the methods of Group II, as they contain additional unrecited ingredients (neural growth factor and neurotherapeutic agent), thus an extension of search would be necessary. Because these inventions are

independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and X, XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Group X (composition comprising a VEGF-C protein and a neural growth factor) or XII (composition comprising a VEGF-C protein and a neurotherapeutic agent) are not necessary to carry out the methods of Group II (administering a VEGF-C polynucleotide), thus the inventions are distinct. Moreover while the products of Groups X and XII would be used in protein therapy, Group II encompasses gene therapy. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case neural stem cells could be used as sources of neurological proteins or to screen compounds for neurotoxicants, thus the method is distinct from the product. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and V-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the product of Group III (purified and isolated neural cells) is not necessary to carry out the methods of Groups V (administering a VEGF-C or VEGF-D protein and a neural growth factor, VI (administering a VEGF-C or VEGF-D polypeptide and a neural growth factor), VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent) VIII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent) or IX (administering a VEGF-C inhibitor), thus the inventions are distinct. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and X-XIII are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups X (composition comprising a VEGF-C product), XI (VEGF-C protein and a neural growth factor), XII (VEGF-C protein and a neural growth factor) or XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) do not share any common structural, technical or functional feature with that of Group III (purified and isolated neural stem cells), thus the inventions are distinct. Because these inventions are independent or distinct for the reasons given above and the inventions

require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions IV and V-IX are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, Groups V (administering a VEGF-C or VEGF-D protein and a neural growth factor), VI (administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor), VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent), VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent) and IX (administering a VEGF-C inhibitor) do not share any method steps with Group IV, which is drawn to administering neural stem cells. Furthermore, restriction is deemed to be proper because the method steps in Groups I and V-IX are not co-extensive, thus a search and examination of all six methods in one patent application would result in an undue burden, since the searches for the different methods are not co-extensive. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions IV and X-XIII are unrelated inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups X (composition comprising a VEGF-C protein

and a neural growth factor), XI (composition comprising a VEGF-C polynucleotide and a neural growth factor), XII (composition comprising a VEGF-C protein and a neurotherapeutic agent) or XIII (composition comprising a VEGF-C protein and a neurotherapeutic agent) are not necessary to carry out the methods of Group IV (administering neural stem cells), thus the inventions are distinct. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V and VI, VIII and IX are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of Groups VI (administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor), VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent) or IX (administering a VEGF-C inhibitor) do not share any method steps with Group V (administering a VEGF-C or VEGF-D protein and a neural growth factor). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V and VII are directed to related but distinct methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially

different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, both Group VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent) and Group V (administering a VEGF-C or VEGF-D protein and a neural growth factor) are drawn to administering a VEGF-C or VEGF-D protein **and an additional agent**. The added agents are different in each case, thus there is an extension of search. Because these inventions are independent or distinct for the reasons given above and the searches are not coextensive, restriction for examination purposes as indicated is proper.

Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of Group X could be used to generate antibodies or as a growth factor in cell culture. Because these inventions are distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V and XI-XIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups XI (composition comprising a VEGF-C polynucleotide and a neural growth factor), XII (composition comprising a VEGF-C protein and a

neurotherapeutic agent and XIII (a composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are not disclosed as being used for the method of Group V (administering a VEGF-C or VEGF-D protein and a neural growth factor), thus the searches would not be co-extensive. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VI and VIII are directed to related but distinct methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have materially different design, mode of operation, function, or effect. See MPEP § 806.05 (j). In the instant case, Groups VI (administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor) is distinct from Group VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent), however the Groups overlap in scope, because each are drawn to the administration of VEGF-C or VEGF-D polynucleotide **and an additional agent**. The additional agents are different for each Group, thus the method steps are not identical in each case, the searches are not co-extensive and a different search must be carried out for each invention, especially in the non-patent literature, which is not classified. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VI and VII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of Groups VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent) and IX (administering a VEGF-C inhibitor) do not share any common method steps with Group VI (administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VI and X, XII, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions. In the instant case, the products of Groups X (composition comprising a VEGF-C protein and a neural growth factor), XII (composition comprising a VEGF-C protein and a neurotherapeutic agent) and XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are not disclosed as being used for the method of Group VI (administering a VEGF-C or VEGF-D polynucleotide and a neural growth factor), thus the searches would not be co-extensive. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VI and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of gene therapy could be practiced with other materially different products. In addition, a VEGF-C or VEGF-D polynucleotide could be used to make the protein recombinantly and the neural growth factor could be used in cell culture. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VII and VIII-IX are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of Groups VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent) and IX (administering a VEGF-C inhibitor) do not share any common method steps with Group VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search that is not co-extensive (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VII and X, XI, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups X (composition comprising a VEGF-C protein and a neural growth factor), XI (composition comprising a VEGF-C polynucleotide and a neural growth factor and XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are not disclosed as being used in the method of Group VII (administering a VEGF-C or VEGF-D protein and a neurotherapeutic agent). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group XII (VEGF-C protein and a neurotherapeutic agent) could be used in neural cell culture. In addition, protein therapy can be practiced with products other than that taught in Group XII. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

Inventions VIII and IX are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of administering a VEGF-C inhibitor does not share any common method steps with that of Group VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent). Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VIII and X-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups X (composition comprising a VEGF-C protein and a neural growth factor) XI (composition comprising a VEGF-C polynucleotide and a neural growth factor) and XII (composition comprising a VEGF-C protein and a neurotherapeutic agent) are not disclosed as being used in the method of Group VIII (administering a VEGF-C or VEGF-D polynucleotide and a neurotherapeutic agent). Because these inventions are independent or distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

Inventions VIII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group XIII (VEGF-C polynucleotide and a neurotherapeutic agent) could be used as an additive in neural cell culture. In addition, gene therapy can be practiced with different compositions than that of Group XIII. Because these inventions are distinct for the searches are not co-extensive, restriction for examination purposes as indicated is proper.

Inventions IX and X-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups X (composition comprising a VEGF-C protein and a neural growth factor), XI (composition comprising a VEGF-C and a neurotherapeutic agent), XII (composition comprising a VEGF-C protein and a neurotherapeutic agent) and XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are not disclosed as being used in the method of Group IX (administering of a VEGF-C inhibitor). Because these inventions are independent for the reasons given above and the inventions require different fields of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions X and XI, XIII are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups XI (composition comprising a VEGF-C polynucleotide and a neural growth factor) and XIII (composition comprising a VEGF-C polynucleotide and a neurotherapeutic agent) are different from that recited in Group X, VEGF-C protein and a neural growth factor. The protein of Group X and the polynucleotides of Groups XI, XIII are patentably distinct inventions because polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. The search of the proteins and the polynucleotides are not coextensive. In the patent literature, proteins and polypeptides have separate classifications. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive and requires a different field of search (see MPEP § 808.02), thus restriction for examination purposes as indicated is proper.

Inventions X and XII are directed to related but distinct products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the

inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products share a common structural feature of a composition comprising a VEGF-C protein **and another agent**, a neural growth factor (Group X) or a neurotherapeutic agent (Group XII). A neurotherapeutic agent encompasses a huge number of possible pharmaceuticals, proteins or molecules that have therapeutic value, whereas a neural growth factor would generally be recognized as a protein, thus the scope of Group X is much broader than that of Group XII. Second, because the material difference in design of the compositions, they could have different effects. Finally, the difference in the added agents in each of the compositions requires an extended search in the case of Group X, which is broader in scope, thus the searches are not co-extensive. Because these inventions distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

Inventions XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions are patentably distinct because proteins (Group XII), which are composed of amino acids, and polynucleotides (Group XI), which are composed of purine and pyrimidine units, are structurally distinct molecules. Furthermore, the search for proteins and the polynucleotides is not co-extensive. In the patent literature, proteins

and polynucleotides have separate classifications. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions XI and XIII are directed to related but distinct products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products share a common structural feature of a composition comprising a VEGF-C polynucleotide **and another agent**, a neural growth factor (Group XI) or a neurotherapeutic agent (Group XIII). A neurotherapeutic agent encompasses a huge number of possible pharmaceuticals, proteins or molecules that have therapeutic value, whereas a neural growth factor would generally be recognized as a protein, thus the scope of Group XIII is broader than that of Group XI. Second, because the material difference in design of the compositions, they could have different effects. Finally, the difference in the added agents in each of the compositions requires an extended search in the case of Group XIII, which is broader in scope, thus the searches are not co-

extensive. Because these inventions distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

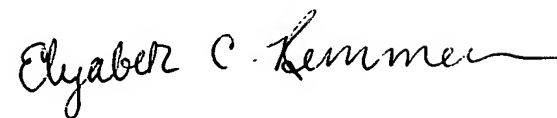
Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christina Borgeest, Ph.D.



**ELIZABETH KEMMERER
PRIMARY EXAMINER**